MAICO Diagnostic GmbH

Operating Instructions
MAICO MI 26

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Operating Instruction MI 26

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Operating Instruction MI 26

1 Introduction

Thank you very much for purchasing a quality product from the MAICO family. This automatic Tympanometer MAICO MI 26 is manufactured to meet all quality and safety requirements.

In designing the MAICO MI 26 we placed particular importance on making it a user-friendly device, meaning its operation is simple and easy to understand. And because all functions are software controlled, upgrading later to new, extended measurement functions will be simple and inexpensive. That means that you have invested in a device that will adjust to your future needs.

This user manual should make it as easy as possible for you to become familiar with the functions of the MAICO MI 26. The description of the position (5) (e.g.) of controls, displays and connections, found again in the text, will make it easier for you to learn how to operate the MAICO MI 26.

If you have problems or have ideas for further improvements, please get in touch with us. Simply call.

Your MAICO team

2 Description

2.1 Purpose

The MI 26 is an automatic instrument that is designed for tympanometric and audiometric pure tone screening. Tests done in the tympanometric screening mode measure middle ear mobility and ipsilateral acoustic reflex. Contralateral acoustic reflex is available as an option. Test results are displayed on the front panel LCD (liquid crystal display) screen and may be printed.

The MI 26 not only performs all of these impedance screening functions but has the capability of audiometric pure tone screening. Tests done in the audiometric pure tone screening mode measure hearing response levels. The MI 26 offers a full range of frequencies and levels for complete air conduction hearing screening

The design of the MI 26 allows rapid and reliable measurements. This equipment is designed for middle ear function screening.

2.1.1 PC-Interface:

An USB-interface for data transfer to a connected computer is built in.

The MAICO MI 26 is laid out according to the EN of 60 601-1 „medically electrical devices ". In order to ensure this also with attached computer, the computer must correspond to the EN 60 601-1. If not, please look to chapter 15.5 Patient safety.

2.2 Tympanometry

Tympanometry is the objective measurement of middle ear mobility (compliance) and pressure within the middle ear system. During the test, a low-pitched probe tone (226 Hz) is presented to the ear canal by means of the hand-held probe. This tone is used to measure the change in compliance in the middle ear system while the air pressure is varied automatically from a positive value (+200 daPa) to a negative value (-400 daPa max.).

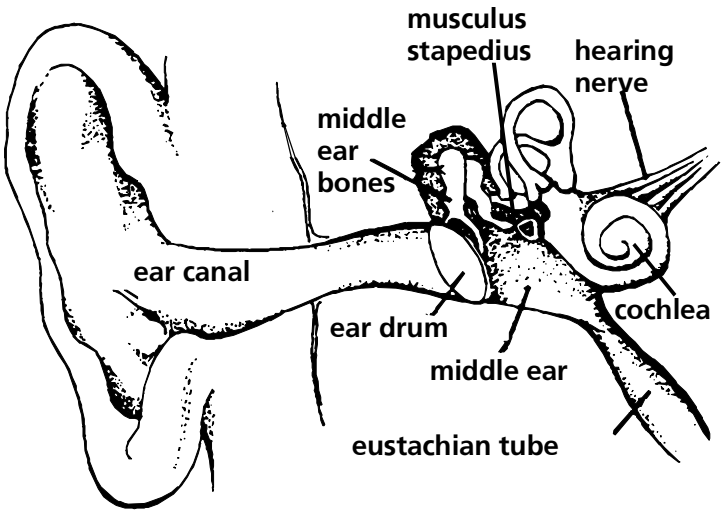


Figure 1

Maximum compliance of the middle ear system occurs when the pressure in the middle ear cavity is equal to the pressure in the external auditory canal. This is the highest peak of the curve as it is recorded on the chart. The position of the peak

on the horizontal axis and on the vertical axis of the chart will provide diagnostic information regarding the function of the middle ear system. Examples of normal and abnormal tympanograms can be found in a later section of this manual.

Gradient calculations are reported as the tympanogram width at half of peak compliance expressed in daPa. A "limits" box is available on both the display and printout to aid in diagnosis. Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml). Air pressure is measured in deca-Pascals (daPa).

NOTE: 1.02 mm H_2O = 1.0 daPa.

2.3 Acoustic Reflex

An acoustic reflex, or contraction of the Stapedial muscle, occurs under normal conditions when a sufficiently intense sound is presented to the auditory pathway. This contraction of the muscle causes a stiffening of the ossicular chain which changes the compliance of the middle ear system. As in tympanometry, a probe tone is used to measure this change in compliance.

When the stimulus presentation and measurement are made in the same ear by means of the probe, this acoustical reflex is referred to as an ipsilateral acoustic reflex. When the stimulus presentation and measurement are made in opposite ears, the reflex is referred to as a contralateral acoustic reflex.

For best results, this reflex measurement is automatically conducted at the air pressure value where the compliance peak occurred during the tympanometric test. Stimulus tones of varying intensities at 500, 1000, 2000 or 4000 Hz are presented as short bursts. If a change in compliance greater than 0.05 ml is detected, a reflex is considered present. Because this is an extremely small compliance change, any movement of the probe during the test may produce an artifact (false response). The test result is recorded as **Pass/Fail***,* and in graphical form.

If the tympanometric results display any abnormal findings, the results of the acoustic reflex testing may be inconclusive and should be interpreted with care. Theoretically, a compliance peak is necessary to observe a reflex at peak pressure.

2.4 Audiometric Pure Tone Screening

The purpose of this test is to measure the intensities of pure tones of various frequencies that a listener is just barely able to detect in an otherwise quiet environment. During screening, tones can be presented at a determined frequency and intensity. The MI 26 can be used to find the lowest response level (threshold) at each frequency. Pass/fail criteria can be decided by following the established standards for your organization.

3 Getting started

Your MI 26 was carefully inspected and packed for shipping. However, it is good practice to thoroughly inspect the outside of the shipping container for signs of damage. If any damage is noted, please notify the carrier immediately.

3.1 Unpacking

Remove the accessories. Carefully remove the instrument from the shipping carton. Remove the instrument from the plastic bag and inspect the case for any damage. Notify the carrier immediately if any mechanical damage is noted. This will assure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. When the adjuster has completed the inspection, notify the MAICO Special Instrument Distributor you purchased this unit from.

Save all the original packing material and the shipping container so the instrument can be properly packaged if it needs to be returned for service or calibration.

Accessories	**Part No.**
Hand-held probe	802 172
24-count eartips kit:	705 069
(4) yellow, 7 mm	705 056
(4) green, 9 mm	705 057
(4) white, 11 mm	705 058
(4) yellow, 13 mm	705 059
(4) green, 15 mm	705 060
(4) blue, 18 mm	705 061
Thermal printer paper	705 078
Calibration test cavity	705 167
TDH 39 headset	4 687
Patient response switch	801 012
Optional Accessories:	
Soft-sided carrying case	1035-3002

3.2 Environmental conditions for the MI 26

The MI 26 should be operated in a quiet room.

The test room must be at normal temperature, usually 15°C / 59°F to 35°C / 95°F, and the instrument should be switched on about 10 minutes before the first measurement to guarantee precise measuring results. If the device has been cooled down (e.g. during transport), please wait until it has warmed up to room temperature.

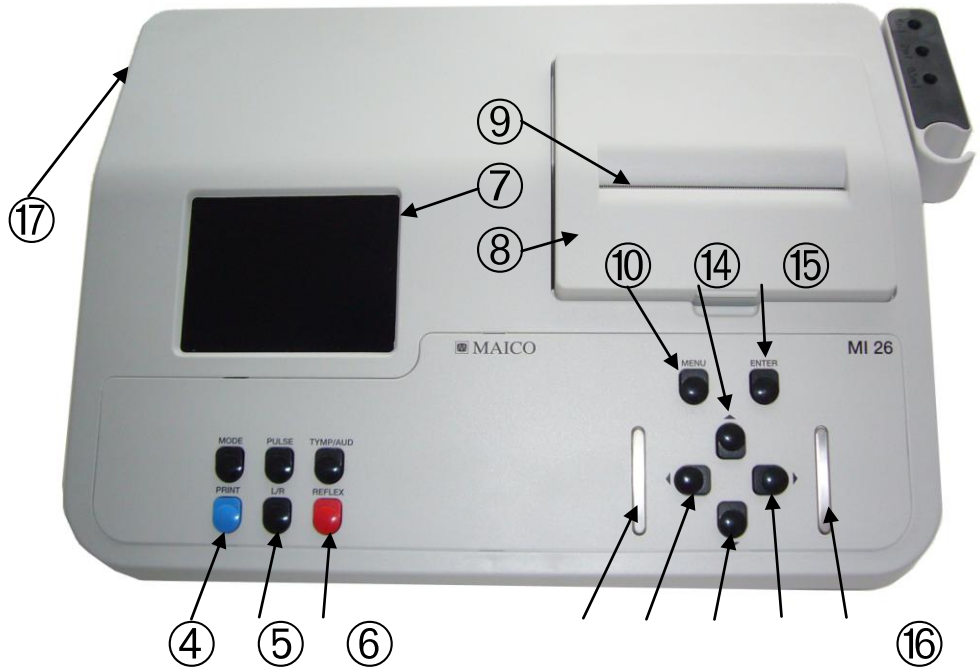
3.3 Preparing the MI 26 for use

3.3.1 Connect probe and accessories

- Connect the probe cable to socket (C) on the rear of the instrument.
- Insert the plug into the socket and secure the connection by fastening the two screws of the connector.
- Insert the pressure tube into the socket (B) and press it until it is secure on the socket.
- Connect the headset cable to socket (F) and (G) on the rear of the instrument.
- Connect the cable of the patient response switch to socket (H) on the rear of the instrument.
- Put the enclosed mains cable into the power connection socket (A) and its main plug into a power socket. The instrument is now operational.

Figure 2
The probe of the MI 26

4 Getting familiar with the MI 26



4.1 The MI 26 Front Panel Controls

1. **Mode** = Changes Mode from Presenter to Interrupter.
2. **PULSE** = Turns pulse tone on or off for audiometric testing.
3. **TYMP/AUD** = Changes modes between tympanogram or audiometric testing
4. **PRINT** = Prints the test results.
5. **L/R** = Changes test ears from left to right, or right to left for tympanogram or audiogram. Press and hold for 2 seconds to erase stored tests.
6. **REFLEX** = Changes the reflex testing modes from IPSI to CONTRA or NO REFLEX.
7. LCD-Display
8. Printer cover
9. Paper slot with paper cutting edge
10. **MENU** – Enter the main menu screen
11. ◂ = Decreases the frequency (Hz) for audiometric testing.
12. ▾ = Decreases the intensity level (dB) of reflex or audiometric testing.
13. ▸ = Increases the frequency (Hz) for audiometric testing.
14. ▴ = Increases the intensity level (dB) of reflex or audiometric testing.
15. Enter ↩ - Enter the highlighted menu or the highlighted option.
16. Presenter or interrupter button (depends on mode you have chosen)
17. =**ON/OFF SWITCH** – Power switch; 1 is ON, 0 is OFF

How to use the extended functions is described in chapter 11: “Individual Setup of the MI 26."

4.2 The MI 26 Rear Panel Connections

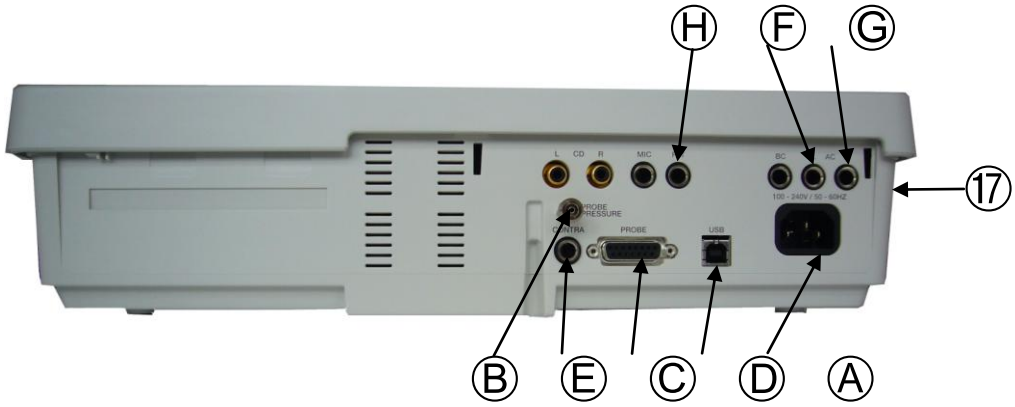


Figure 4
Connectors at the rear of the MI 26

A. AC POWER - Connection for AC power cord. (100…240 V~50/60 HZ)

B. PRESSURE TUBE CONNECTION - Pneumatic connection for the probe cable.

C. PROBE CABLE CONNECTION - Connection for probe cable to rear panel.

D. USB CONNECTOR - Connection for computer interface.

E. CONTRALATERAL PHONE CONNECTION – Jack for contralateral reflex phone, (optional).

F. AC (R) - Jack for right (red) audiometer phone.

G. AC (L) - Jack for left (blue) audiometer phone.

H. PAT – Jack for patient response switch

4.3 Switch the instrument on

Switch the main switch (17) on. The LCD will show the type of instrument and software version for a moment. Then the basic measuring Figure appears.

The MI 26 should be switched on about 10 minutes before the first measurement to guarantee precise measuring results. If the device has been cooled down (e.g. during transport), please wait until it has warmed up to room temperature.

4.3.1 The display of the MI 26

The test result is shown during the measurement on the LCD. The measurements are saved automatically and can be printed out in a fast and quiet way with the integrated printer.

In Figure 5 the initial empty measurement screen is shown. The measurement screen shows actual settings, test results and the graphical display of the tympanogram and reflexes.

From left to right the top line shows the type of test (impedance is shown in Figure 5), the selected test ear (left or right) and the selected reflex test (*ipsi*, *contra* (optional) or *tympanogram* if no reflex test is selected).

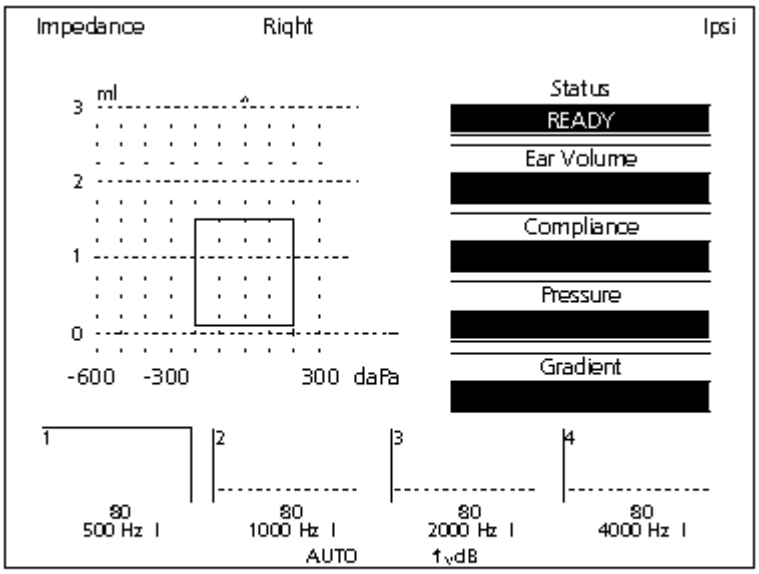


Figure 5
The measurement screen of the MI 26

At the left center, the graph of the tympanogram is shown. At the right, five boxes show the status and test values.

The upper box shows the actual status of the instrument:

READY - means that the instrument is ready for testing
IN EAR - shows that the probe is inserted in the ear
TESTING - means that the test is in progress
BLOCKED - means that probe is blocked in the ear
LEAKING - indicates that the ear tip does not have a proper seal

The boxes below "**Status**" show the volume of the ear canal, the compliance, the pressure at maximum compliance and the gradient of the tympanogram when the test has been completed.

The four boxes at the bottom of the screen, marked 1 to 4, show the graphical reflex curves after the test. Below each box the test level (Figure 5: 80 dB), and the test frequencies (Figure 5: 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) are displayed. After the frequency an "I" shows that ipsilateral testing is selected.

Finally, at the very bottom in Figure 5 the word "**AUTO**" and 80 dB scale is shown. This means that the reflex test level will increase automatically until a reflex is found or the maximum level is reached. With the arrow keys, the test levels can be changed to a fixed level. The dB values below the boxes change accordingly. It

is possible to have fixed levels from 70 dB to 100 dB or **Auto**.

4.4 Calibrate the probe

With the calibration test cavity you can adjust your impedance with measuring instrument. Do the same when you change the probe (from screening probe to diagnostic probe and vice versa). The calibration is very easy and takes only 20 seconds.

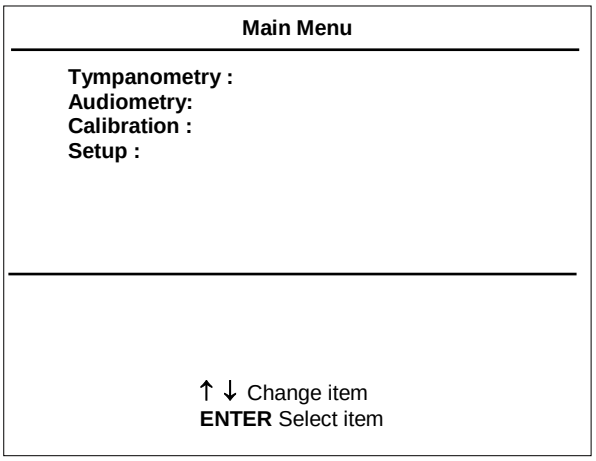


Figure 6
Main Menu

Press the menu key (10) and the main menu (Figure 6) appears on the LCD. Select the menu option **CALIBRATION** with the arrow keys and press **Enter**. Follow the instructions on the LCD as shown in Figure 7.

Put the probe tip (S) without ear tip into the hole of the test cavity labeled 0.5 ml. The text on the display will request that the probe tip be inserted for the 2 ml calibration. Put the probe tip in the 2 ml cavity. Do this again for the 5 ml volume. The MI 26 will automatically change into the tympanometry mode. The basic menu for the impedance measurement appears again and you are ready for measurements.

If the error information **CAVITY CALIBRATION OUT OF RANGE** appears during the calibration, please make sure the opening of the probe tip is clean and try to recalibrate the probe. If the error information appears again, the probe or the instrument are probably defective. Inform your distributor to get immediate help.

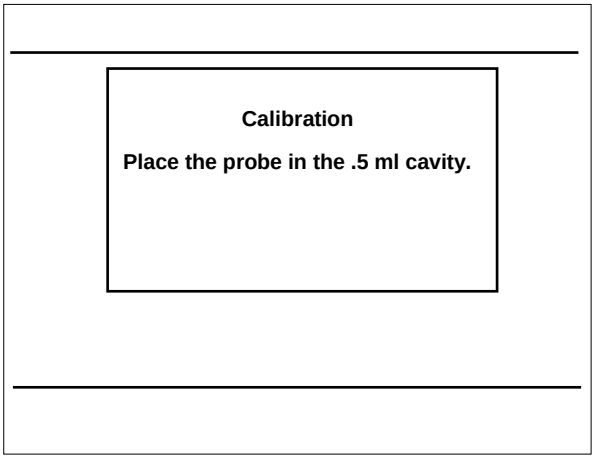


Figure 7
The Calibration screen

4.5 Getting familiar with the probe

The probe of the MI 26 is shown in Figure 8. The probe head is adjustable to three angles (0°, 60° and 80°). It is adjusted by turning the locking screw (T) at the bottom of the probe using a coin or a screw driver. Adjust the probe head (P) by pulling it into the required position until it rests. After it is set to the required position tighten the locking screw again.

The probe button (M) can be used to select the required test ear.

The color of the (O) control light changes accordingly to red (right ear) or blue (left ear).

The color of the control light on the probe indicates your current operation.

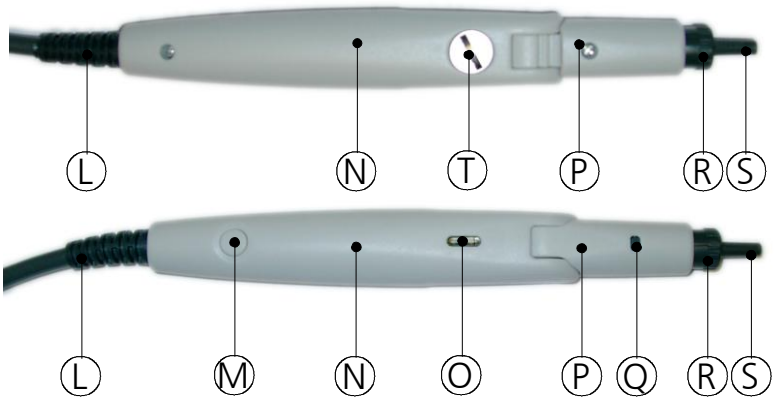


Figure 8
The probe of the MI 26

A red control light indicates that the right ear is selected. The system is ready for measurements. As soon as you have put the probe into the auditory canal the control light turns green. Now the test is in progress. Do not change the position of the probe until the green control light goes out indicating the end of the measurement.

A blue control light indicates that the left ear is selected. The system is ready for measurements. As soon as you have put the probe into the auditory canal the control light turns green. Now the test is in progress. Do not change the position of the probe until the green control light goes out indicating the end of the measurement.

A yellow control light indicates an error. The kind of the error is indicated on the LCD under status:

LEAKING: The ear tip is not sealed in the auditory canal. Change the position of the probe until the control light turns green. If you are not successful, use a bigger ear tip.

BLOCKED: Indicates blockage in the probe opening. Change the position of the probe so that it points straight into the auditory canal until the control light turns green. If you are not successful, check that the probe is not blocked with ear wax.

The complete probe insert can be changed by pressing the release button (Q).
If the probe tip is clogged, you can remove it by opening the fixation ring (R).

After cleaning the probe tip or attaching a new one, the tip must be fixed again by fastening the fixation ring.

4.6 Choose an appropriate ear tip

Choose an ear tip of the appropriate size from the ear tip set. Put the ear tip tightly on the probe tip. The probe tip should close up with the end of the ear tip. It should not disappear with more than about 1 mm in the ear tip or just out of the ear Tipp.

By choosing an appropriate ear tip and placing it correctly on the probe you create the basic conditions for measurements without problems and mistakes.

Now all preparations are concluded and you can start the impedance and reflex measurement. Please read the following chapters.

5 How to create a Tympanogram

In the following paragraph we will deal shortly with the principle and the background of the impedance measurement to create a better understanding. If you want to begin the measurements immediately, just skip this paragraph and continue reading section "Preparing the Measurements."

5.1 The basics of the impedance measurement

The impedance measurement assists in diagnosing of the condition of the middle ear and can therefore not be compared directly with other audiometrical tests such as sound or speech audiometry which assists in the measurement of hearing. Furthermore the impedance measurement is an objective measuring method which does not depend on the cooperation of the test person and can therefore not be falsified by the patient.

The two most important impedance measuring methods possible with your MI 26 are tympanometry and the measurement of the Stapedius reflex which is discussed in chapter: "How to measure the Stapedius reflex."

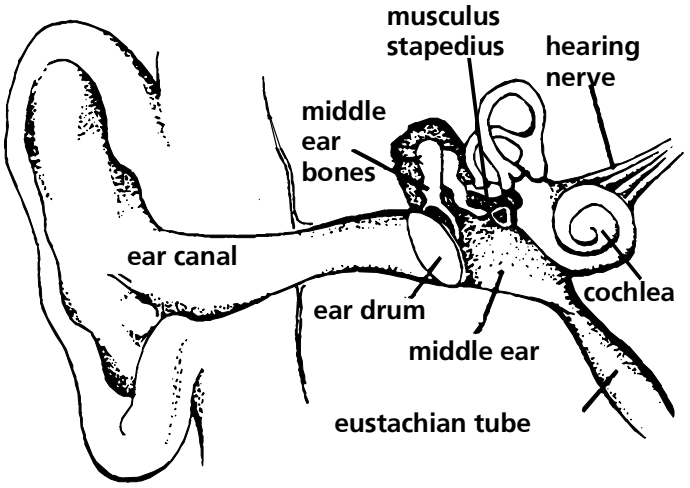


Figure 9
The middle ear

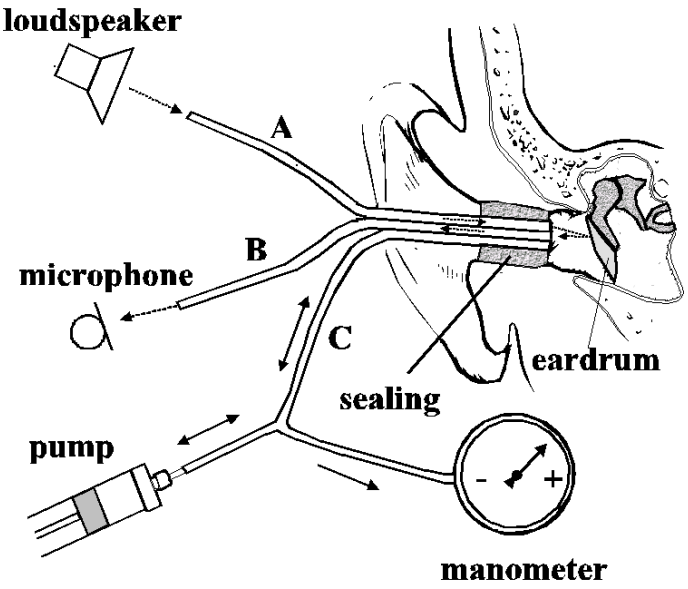


Figure 10
Principle of the impedance measurement

The impedance measurement examines the acoustic resistance of the middle ear. If the eardrum is hit by a sound, part of the sound is absorbed and sent via middle ear to the inner ear while the other part of the sound is reflected. The stiffer the eardrum is the more sound is reflected and the less sound reaches the inner ear. Inside the probe of the impedance measuring instrument a small loudspeaker is installed which emits a low frequency sound through a tube (Figure 10: A) into the auditory canal before the eardrum**.** Another tube (Figure 10: B) is connected to the microphone inside the probe which receives the sound. Together with a third tube (Figure 10: C), all three are inserted nearly to the eardrum and are made airtight against outside pressure by the ear tip. A manometer and a pump, which can produce both positive and negative pressure, are connected with tube **C**. Less sound is reflected to the microphone when the eardrum is stiff and the eardrum transmits the majority of the sound via the middle ear to the inner ear. The highest compliance is normally reached with an air pressure corresponding to the outside pressure.

When performing tympanometry during a measurement, a continuous change of positive and negative pressure is produced by the pump of the instrument in the outer auditory canal. The compliance is measured simultaneously and shown in a diagram (the tympanogram) which illustrates the compliance in ml over the pressure in daPa. In Figure 11, the area for normal tympanogram curves is hatched. Here you can see that the highest compliance is reached with normal pressure. When you create positive and negative pressure the eardrum stiffens - the compliance decreases.

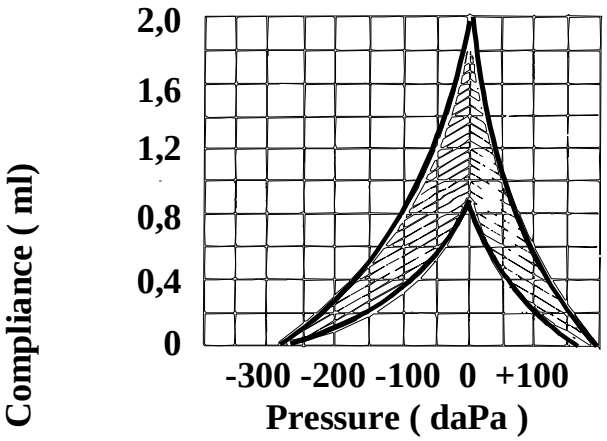


Figure 11
Tympanogram
(normal curve area is hatched)

So you can draw conclusions on the condition of the middle ear from the form and the values of the tympanogram.

5.2 Preparing the patient

Explain to the patient that the measurement is painless and that nothing enters the auditory canal. The patient does not have to respond when there are loud test sounds or when the pressure in the auditory canal changes. In no case should the patient swallow, chew or move during the measurement.

5.3 Preparing the measurement

The LCD shows the empty measurement screen for the right ear and the control light of the probe turns red. To measure the left ear, change the side by pressing the **L/R**-key or the probe button (M). Then the selected test ear shown in the middle-top of the LCD will change from **Right** to **Left** and the control light of the probe will turn blue. Switch off the reflex measurement by pressing the **Reflex**-key. (6)

The word **Tympanogram** (see Figure 12) must appear at the right top of the display. Make sure the auditory canal is clear. Choose the right ear tip according to the size of the auditory canal and put it firmly onto the probe Tipp.

Measuring the tympanogram

Take hold of the top of the outer ear and pull it back. Insert the probe with the ear tip into the auditory canal until the control light of the probe is green indicating the start of the test. Do not move the probe until the green light goes out; the patient must not swallow or speak during the measurement. During the test the LCD will display how the tympanogram is written on the left side and then how the values appear on the right side. After about 4-5 seconds the test is completed and the green light turns off. Now you can remove the probe from the ear.

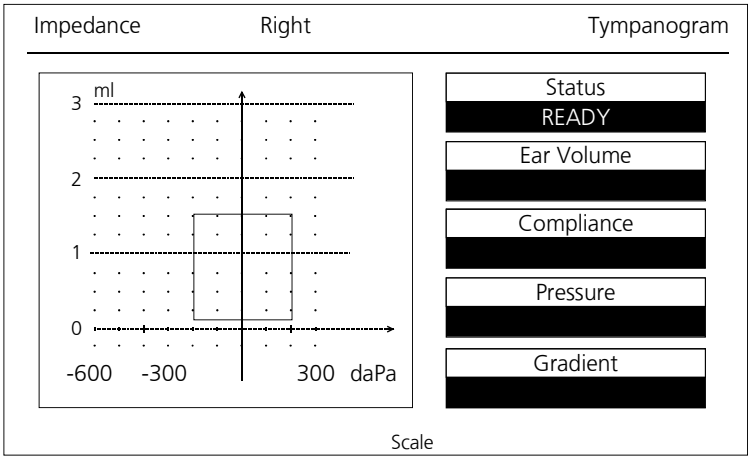


Figure 12
Measurement screen (only Tympanogram)

If an error occurs during the measurement the test will stop. If leakage occurs, the control light of the probe turns yellow and **Leaking** will appear under **Status.** If the probe is blocked, the control light of the probe turns yellow and **Blocked** will appear under **Status**. Please proceed as described in chapter 3.6 "Getting familiar with the probe." To measure the other ear, change the side by pressing the **L/R**-key or the probe button and repeat the measuring procedure described above with the other ear.

5.4 How to evaluate the tympanogram display

After having completed a measurement you can see the results on the LCD.

On the left side of the display you see a graph of the tympanogram. The area surrounded by the box is valid for "normal" tympanograms. You can change the area or turn it off. For details see chapter 11 "Individual Setup of the MI 26."

In the top-middle of the LCD, the words **Right** or **Left** indicate the ear chosen at the moment.

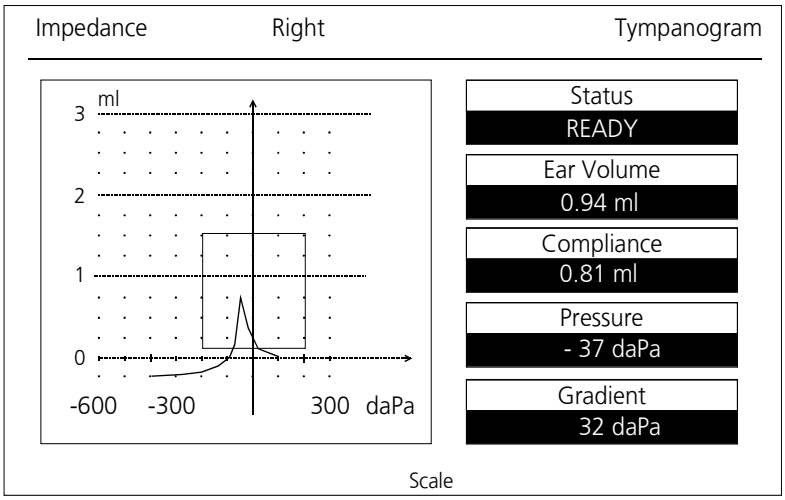


Figure 13
Display of a normal Tympanogram

Tympanometer (at the top right) - indicates that the reflex measurement has been switched off.

In the boxes to the right the following test measurements are displayed:

Ear Volume - indicates the volume of the section of the auditory canal between the ear tip and the eardrum in ml (in the example 0.94 ml).

Compliance - indicates the maximum value of the compliance from the tympanogram in ml (in the example 0.81 ml).

Pressure - indicates the pressure with the highest measured compliance (in the example -37 daPa).

Gradient - calculations are reported as the tympanogram width at half of peak compliance expressed in daPa (in the example 32 daPa).

5.5 How to print the test result

After the end of a test you can print the results for your records by pressing the **Print** button (4). The quiet thermal printer prints out the example used in the previous paragraph in only six seconds.

While the printer is working, no key action is possible and the probe is inactive. Figure 14 shows the printout.

Id No: Patient's Id number.

Date: Actual test date.

Name: Name of the patient.

Examiner: Name of the examiner.

Remarks: Additional information about the test or patient.

All other values and the tympanogram correspond to those you have seen on the LCD (explained on the previous page under 5.4).

The "intelligent" printer control helps you save paper. It will only print out what was actually measured. The printout in the example does not show reflex frequencies because only the tympanogram was measured.

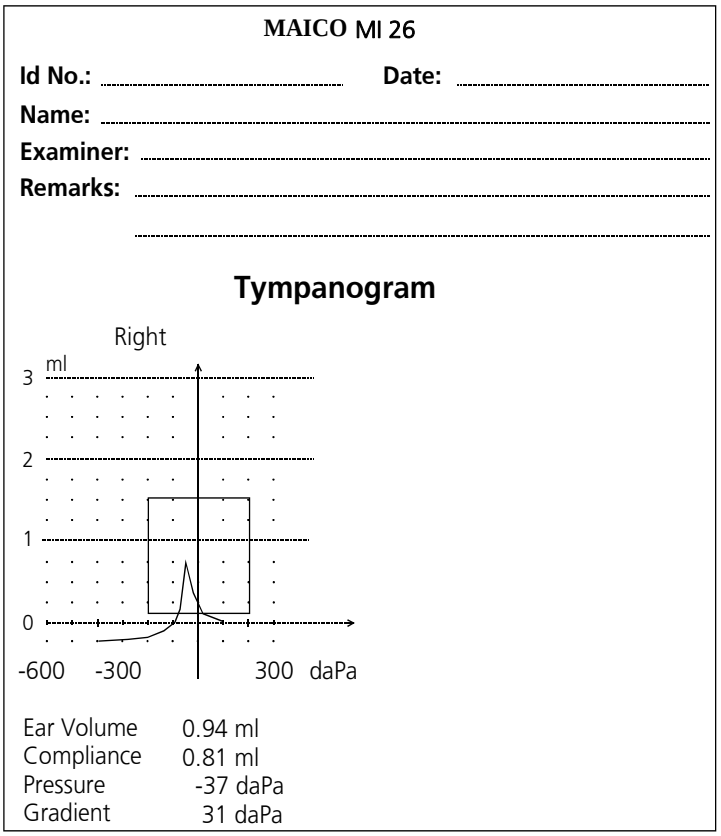


Figure 14
Printout of a normal tympanogram

If you have saved two tympanograms (for example, both the left and the right ear) they are printed side by side.

You can produce as many printouts as you want by pressing the **Print** button several times.

5.6 How to delete the test results

By holding down the **R/L**-key the measurement memory will be deleted. On the LCD the message "**Delete all Data?**" appears. Press **Enter** to delete all patient data. Then the LCD shows an empty measurement screen.

If you press the **Menu** button you return to the measurement screen without deleting the measurement data.

6 How to measure the Stapedius reflex

6.1 The basics of the Stapedius reflex measurement

While tympanometry measures the change of the compliance caused by changing pressure in the outer auditory canal, the Stapedius reflex measurement works with a changing compliance caused by contraction of the Stapedius muscle in the middle ear. The contraction - called Stapedius reflex - causes a decrease in compliance and is caused by loud acoustic stimuli. Regardless whether the acoustic stimulus is active on the left or on the right or on both sides the Stapedius reflex is always binaural, i.e. it occurs in both ears at the same time. The Stapedius reflex is caused in ears of adults with normal hearing with sound pressure levels between 70 and 105 dB.

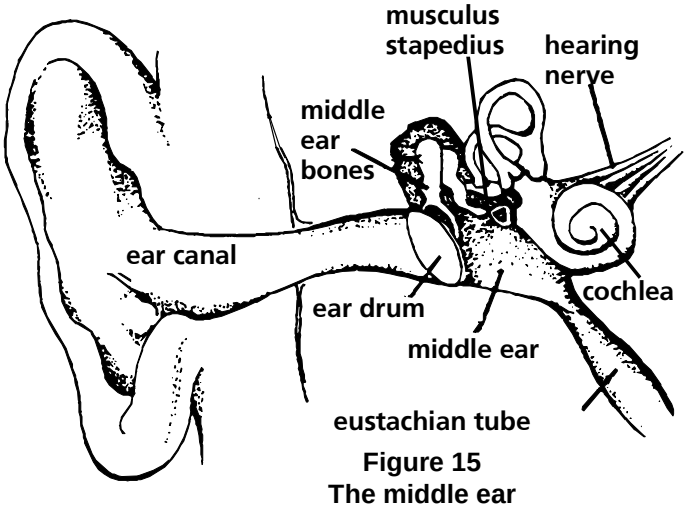


Figure 15
The middle ear

In the probe ear, the reflex method continuously measures the compliance with the pressure which was caused before the highest compliance measurement. Simultaneously the stimulus ear is irritated by the sound which causes the contraction of the Stapedius muscle.

The ipsilateral reflex measurement uses the same ear for the probe and the stimulus. The contra-lateral measurement uses different ears for the probe and the stimulus. The acoustic stimulus is applied to the ear opposite the probe ear.

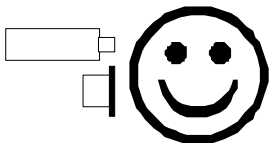


Figure 16 Ipsilateral test

If the applied stimulus causes a reflex, the impedance measuring instrument registers a decrease in compliance in the "probe ear" which indicates a Stapedius reflex at the actual test frequency and the test level. The test level which was set when the reflex occurred is called reflex threshold and is shown in dB_{HL} (dB hearing level).

Figure 17 Contra lateral test

6.2 Preparing the patient

In addition to the general introduction described in chapter 4.2, explain to the patient that loud test sounds will occur during the reflex measurement. It is very important that the patient does not move because a reflex can be registered with a change of compliance of 0.05 ml.

6.3 Preparing the ipsilateral measurement

The LCD shows the empty tympanogram for the right ear and the control light of the probe is red.

To measure the left ear, change the side by pressing the **L/R**-key or the probe button. The selected test ear shown in the middle-top of the LCD will change from **Right** to **Left** and the control light of the probe will turn blue.

Turn the reflex measurement on by pressing the **Reflex**-key. The word **Ipsi** must appear at the right top of the display. The sound stimuli for the reflex measurement are reproduced by the receiver integrated in the probe.

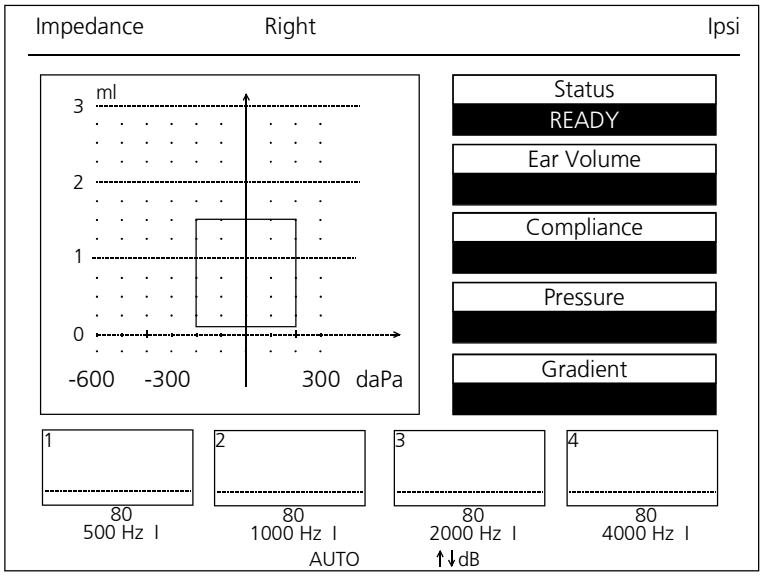


Figure 18
Display Tympanogram + Reflex
(ready for measurement)

Set the desired intensity level with the **down/up** keys. On the LCD below the reflex boxes at the bottom, the selected level in dB (Figure 18: 80 dB) appears. The "**I**" indicates that an ipsilateral test is selected. You can choose between the fixed levels 70, 75, 80, 85, 90, 95 and 100 dB_{HL} and **Auto** with a starting level of 70 or 80 dB_{HL}. If you choose **Auto,** the MI 26 starts with the lowest level 70 dB_{HL} to 100 dB_{HL} and increases the level automatically until a reflex is registered or the maximum value is reached. You can choose your individual starting level and maximum level. If you have chosen a fixed level, the instrument measures only with this level.

Make sure the auditory canal is free.

Choose the correct ear tip according to the size of the auditory canal and put it firmly onto the probe tip.

6.4 Taking the ipsilateral measurement

Carry out the measurement as described in chapter 4.4 "Recording the Tympanogram." The Stapedius reflex is measured after the measurement of the tympanogram. During the measurement of the Stapedius reflex the change of the compliance is represented in real time on the LCD. When the test is finished the curves for the changes of compliance for 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz are shown in four separate graphs at the bottom of the measurement screen (see Figure 19). Below each curve is the test level where a Stapedius reflex was registered automatically. This is indicated by a **Pass** below the frequency. If no reflex was detected, a **Fail** is reported and the maximum level is shown.

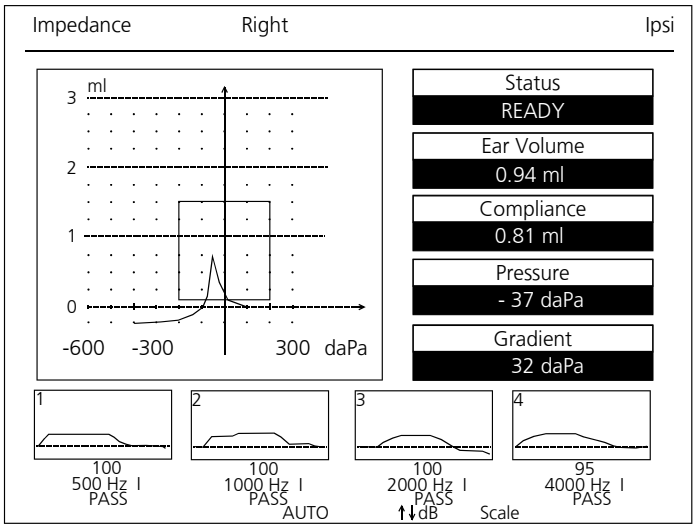


Figure 19
Example of a normal Tympanogram with ipsilateral reflex results

You can judge watching the real time graph if you have a real Stapedius reflex or only disturbance and artifacts. The lower dotted zero-line of a graph indicates the measured compliance without a test sound. All the positive or negative changes of compliance are shown as deviation from the zero-line. If a Stapedius reflex occurs, the compliance decreases and the curve rises. The box which appears during the test symbolizes the threshold at which the MI 26 accepts a change of compliance as a valid Stapedius reflex.

6.5 Preparing the contralateral measurement (optional)

Switch on the contralateral reflex measurement by pressing the **Reflex**-key (the word **Contra** must appear on the right top of the LCD). Here the highest fixed level is 110 dB_{HL} (with TDH 39 contra phone only).

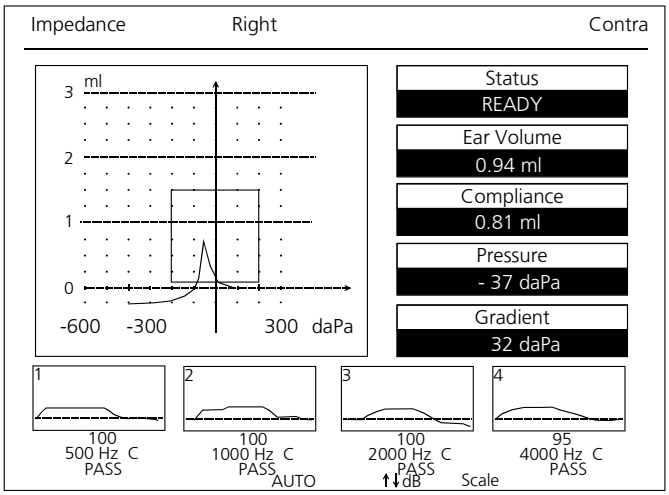


Figure 20
Example of a normal Tympanogram with contralateral reflex results

The contralateral measurement produces more reliable results because the receiver emitting the test signal and the probe measuring the compliance are separated.

If you are using an insert phone for contalateral measurement, put an appropriate ear tip on the insert phone and insert it in the contalateral ear. Continue now as described previously for the ipsilateral measurement.

6.6 How to interpret the reflex display

After having carried out a measurement you can read the recorded values on the LCD.

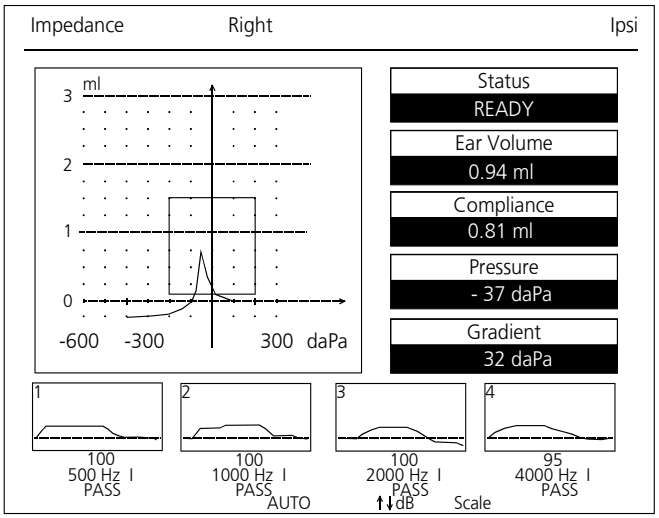


Figure 21
Example of a normal Tympanogram with ipsilateral reflex results

In addition to the tympanogram shown on the left side and the values shown on the right, the results of the reflex measurement appear in the lower part of the display. In the four boxes marked 1 to 4 the Stapedius response is shown graphically. Below each box the test level, the test frequency and the type of the test (**I**=ipsi, **C**=contralateral) are shown. The test result is also shown as **Pass** or **Fail**. In the example in Figure 21, for 500 Hz a Stapedius reflex was registered at 100 dB_{HL} and for 4 kHz at 95 dB_{HL}. If no reflex threshold is registered, **Fail** appears below the frequency.

A correct interpretation of the measuring results can only follow in connection with the tympanogram, the graphic reflex display and other actual data. But in principle a Stapedius reflex indicates that the patient hears on the "stimulus ear" and that the reflex on the "probe ear" functions.

6.7 How to print the test result

After a test, print the results for your documents by pressing the **Print** button. The quiet thermal printer prints out the example in only 12 seconds.

While the printer is working no key action is possible and the probe is inactive.

In addition to printing the text as seen in chapter 5.5 the result of the reflex test is printed out.

The level value (dB_{HL}) at which a reflex had been measured appears below the graph.

If no reflex was registered, **Fail** is printed on the top of the graph behind the test frequency.

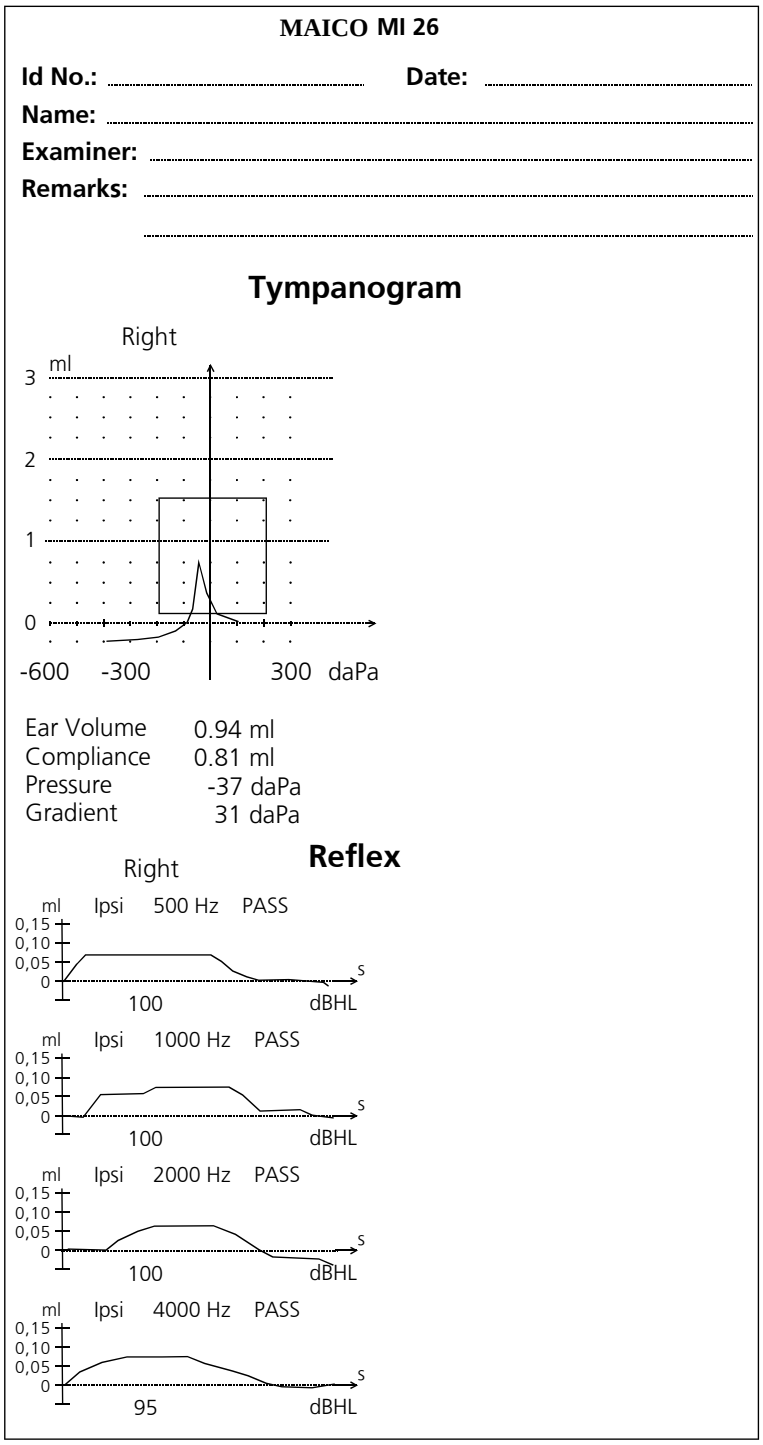


Figure 22
Printout of a normal Tympanogram with ipsilateral reflex measurement

7 Interpreting Test Results

7.1 Understanding the printout

The printout contains the following information:

- Ear volume
- Compliance
- Pressure
- Gradient
- Reflex Test Results (**Pass**, **Fail**) and **ipsi**, **contra** or **tympanogram** (depending on the test you have performed).

This information provides the data you need to interpret the test results.

A graph of the tympanogram is provided (Figure 23) to the test. This graph is a representation of the relative mobility of the middle ear system. The horizontal axis shows the changes in air pressure and the resulting mobility of the system. The compliance is recorded on the vertical axis. This mobility is expressed as a change in the volume of the ear canal in ml.

The reflex is shown in up to four graphics with time on the horizontal axis and the change of the compliance on the vertical axis.

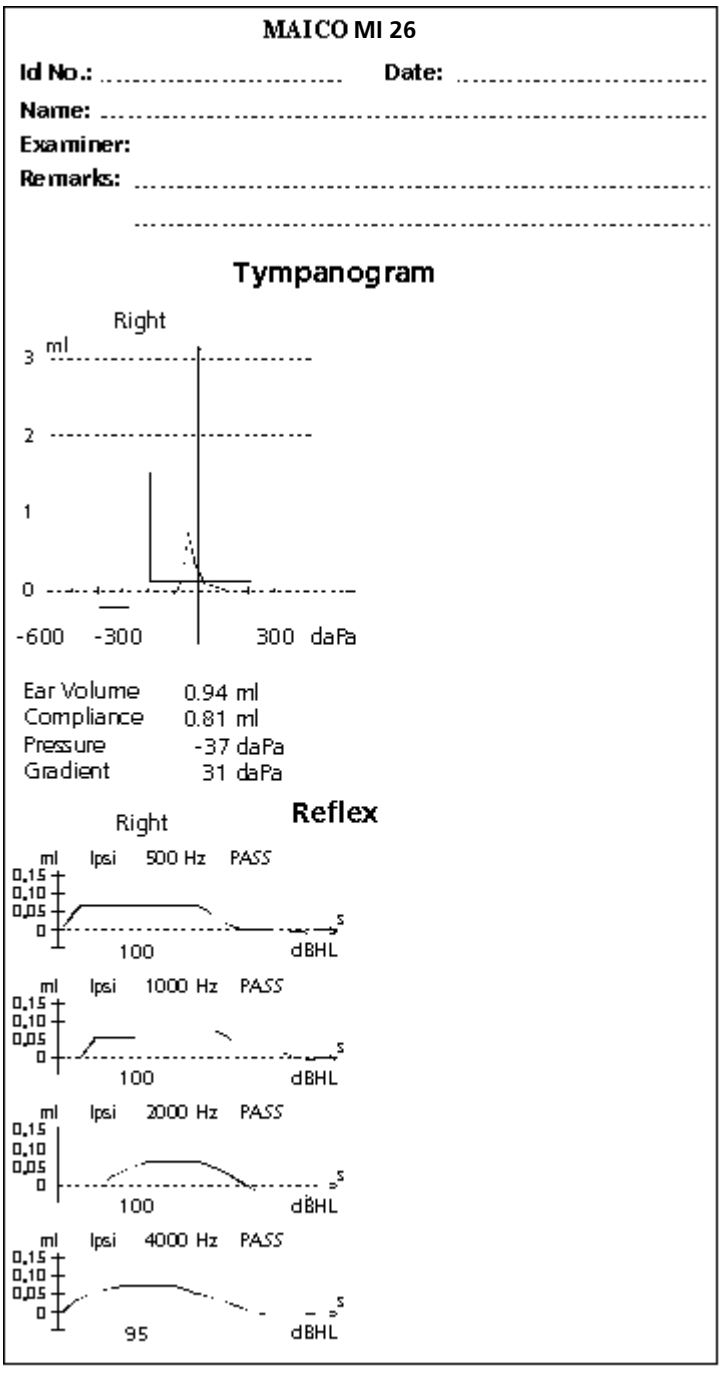


Figure 23
Printout of a normal Tympanogram

7.2 Interpreting the tympanometric test result

As a general rule, values for ear canal volume should be between 0.2 and 2.0 ml (children and adults). A variance will be seen within this range depending on the age and ear structure of the person. For example, a 2.0 ml or larger reading in a small child could indicate a perforation in the tympanic membrane, while it may be a normal reading in an adult. You will become more familiar with the normal ranges when you use the instrument.

The normal range for compliance is 0.2 ml to approximately 1.8 ml. A compliance peak within the range indicates normal mobility of the middle ear system. A peak found outside of these limits may be indicative for one of several pathologies.

Middle ear pressure should be equivalent to ambient air pressure (0 daPa on an air pressure scale). Minor shifts of the peak compliance to the negative may occur with congestion and are rarely to the positive side. Establish criteria for abnormal negative pressure when you become more familiar with using the equipment. It is generally accepted that negative pressure of greater than -150 daPa indicates a referral for medical evaluation. A normal tympanogram is seen on the previous page in Figure 23.

7.3 Abnormal Values

It is the purpose of this section to provide samples of tympanograms which reflect abnormal states of the middle ear mechanism. It is not the intention of this section to provide you with a complete guide to interpreting results. Complete information regarding pathologies and abnormal impedance testing can be found in the literature referenced.

A perforation in the tympanic membrane will cause a high ear canal volume measurement because the instrument will measure the volume of the entire middle ear space. The MI 26 may refuse to run the test, with the probe indicating a volume out of tolerance by illuminating the red light, or a flat tympanogram will be recorded since no movement will occur with a change in air pressure. Without a peak compliance of at least 0.1 ml, the reflex test will not initiate.

An extremely flaccid tympanic membrane or an ossicular chain discontinuity will yield a very high peak compliance in the presence of normal middle ear pressure. Ear canal volume will be normal and the reflex will be absent.

A fixation of the ossicular chain, as in otosclerosis, will produce a tympanogram with very low compliance in the presence of normal middle ear air pressure. Ear canal volume is normal and the reflex is absent.

Middle ear fluid such as serious otitis media will yield a very flat tympanogram with no definite peak and negative air pressure. A resolving case or beginning case may produce a reduced peak in the presence of severe negative middle ear pressure. The ear canal volume is normal and the reflex is either absent or at an elevated level.

Eustachian tube problems in the absence of fluid will show a normal compliance curve, but it will be displayed to the negative side of the tympanogram. Ear canal volume will be normal and the reflex may be present, depending on the degree of impairment.

8 How to test children

The practice of the impedance measurement is difficult especially with small children. You could have problems with the child being restless or afraid of the examination or reacting sensitively to the change of pressure and the loud test sound but also with different conditions of the eardrum and the middle ear which do not appear in ears of adults.

During the measurement the minimum compliance must come to 0.08 ml, if it is less a straight line runs over the zero line.

It is difficult to reach a probe seal with restless children. If the child yawns or cries it is impossible for the instrument to create a stable pressure in the outer auditory canal. In addition speaking causes stapedius muscle reflexes which lead to a permanent change of the compliance of the eardrum.

So the child should be made familiar with the surroundings and the ear being touched by the probe in order to carry out a successful impedance measurement. This could be done by getting in touch with the child and by touching the ear in a playing way with the probe. If you can touch the ear without problems the child will normally accept the probe being inserted.

If the child has accepted the surroundings and the touch of the ear it is important to distract the child's mind from the measurement. Here you can succeed in diverting the child by many different methods. Your phantasy is nearly unlimited, you just have to avoid loud sound.

In case you measure very small children and have to calm them with e.g. a dummy or a tea-bottle the result might be slightly falsified, maybe by a slightly irregular line of the Tympanogram.

9 AUDIOMETRIC PURE TONE SCREENING

9.1 Preparing the Patient for the Test

Before any kind of hearing testing, a brief patient orientation is required. Simply tell the patient to "press the stimulus response button whenever you hear a "beep", then quickly release the button. The patient should sit at a distance of at least 1 m from the device. Eliminate any obstructions which will interfere with the placement of the earphone cushions on the ear (i.e. hair, eyeglasses).

Ensure the headphones are put on correctly. Red side on the right, blue side on the left. Adjust the headband of the headphones so that the receivers are at the correct height (the sound output grid exactly facing the ear canal). Start with the "better" indicated ear at 1 kHz. In the following example we assume that the right is the "better" ear.

9.2 Audiometer Function Recommended Procedures

Turn the POWER switch ON (4), and let warm up 5-10 minutes. Press the TYMP/AUD key to change from the tympanogram mode to the audiogram mode.

Pass/Fail Method:

The initial setting on the LCD screen (see figure 24) will indicate a frequency of 1 KHz and an intensity of 30 dB. Pressing the ▲ ▼ keys will change the intensity levels. Pressing the ◀ ▶ keys will change the frequencies. Holding down these keys will let you scroll through the selections. Pressing the **PULSE** key chooses either pulsed or steady tone.

1. Set the dB level at a predetermined level for a Pass or Fail criteria. (e.g. a level at 20 dB).
2. Present the tone stimulus at 4 different frequencies (e.g. 500, 1000, 2000 and 4000 Hz). You will only present one stimulus per frequency. Instruct the patient to respond by pressing the response switch or raising their hand when they hear the tone. The Response Box on the LCD screen will light if the patient response switch is pressed.
3. If the patient fails at any frequency you may choose to do a presentation at 10 dB higher (30 dB). The patient may then be referred or rescheduled if they fail at two or more frequencies.

NOTE: This is an example only. You must develop a method that fits your situation.

9.3 Hearing Threshold Method (Air Conduction)

The most commonly used hearing threshold procedure is called a modified Hughson-Westlake procedure.

1. Start at 1000 Hz with a level of 0 dB and present a signal for at least 1second. If no response, increase in 10 dB steps until the patient responds.
2. Increase another 10 dB for a confirmation and orientation. If the patient responds again, decrease the presentations in 10dB steps until the patient no longer responds.
3. Increase in 5 dB steps until the patient responds. Once the patient responds, descend 10dB until there is no response. Increase again in 5 dB steps.
4. Repeat until you have 2 out of 3 ascending responses at the same level. Change the frequency and repeat the above procedure until you have the thresholds for the number of frequencies you wish to test.

The hearing threshold is defined as the lowest hearing level at which the patient responds to two out of three ascending stimuli at the same level.

9.4 MI 26 LCD Screen - Audiometer

Press the key TYMP/AUD. The LCD display shows the audiometer screen.

On the top left the actual test frequency (1000 Hz) is shown. On the top right you can see the actual level setting (30 dB). On the top in the middle you find the display fields RESPONSE and STIMULUS.

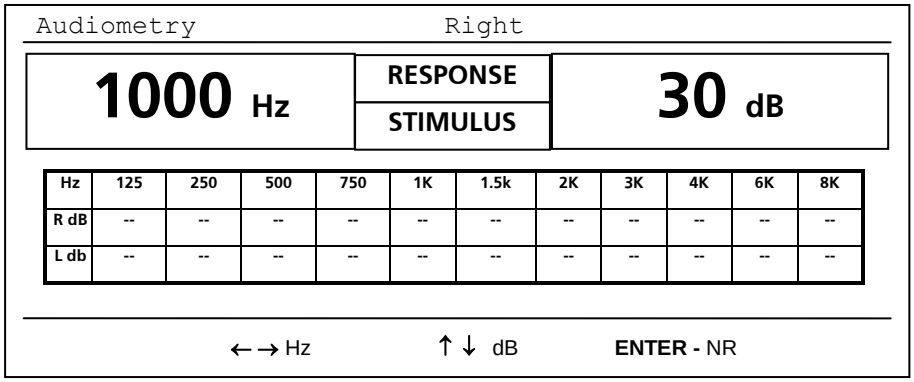


Figure 24
Audiometer LCD Screen

RESPONSE:

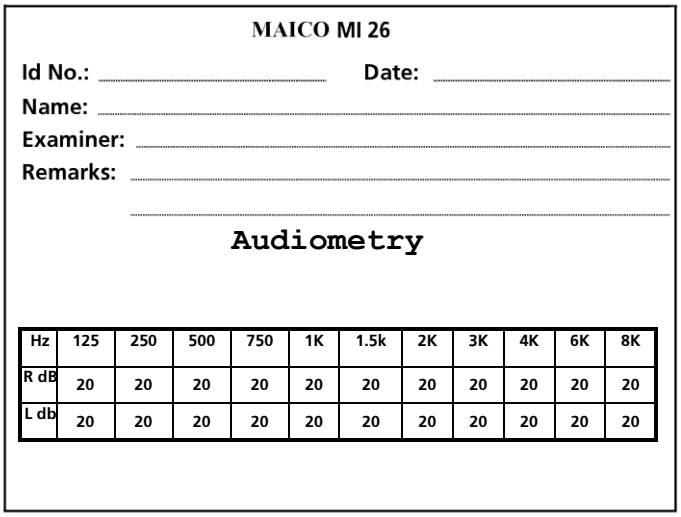
Indicates when the Patient Response Switch has been pressed.

STIMULUS:

Indicates when the operator is pressing either **Tone Presentation** key, presenting the stimulus. When the **PULSE** key is pressed it enables or disables pulsed tone. When in pulsed tone mode, the **STIMULUS** box will flash; in continuous mode the box will highlight until the **STIMULUS** button is released.

9.5 Audiometric Pure Tone Screening Results

Pass/fail criteria for audiometric pure tone screening can be determined by following individual established standards. Since standard levels can vary, a normal or abnormal response level will not be given in this manual. The test results in Figure 25 are an example of a MI 26 audiometric printout.



MAICO MI 26

Id No.: _____ Date: _____

Name: _____

Examiner: _____

Remarks: _____

_____

Audiometry

Hz	125	250	500	750	1K	1.5k	2K	3K	4K	6K	8K
R dB	20	20	20	20	20	20	20	20	20	20	20
L db	20	20	20	20	20	20	20	20	20	20	20

Figure 25
Audiometric Printout

10 Additional Reading

Auditory Disorders: A Manual for Clinical Evaluation
Jerger, Susan, and James Jerger
Boston: College Hill Press, 1981

Handbook of Clinical Audiology
Katz, Jack
Baltimore: William & Wilkins, 1994

Roeser´s Audiology Desk Reference
Roeser, Ross J.
New York / Stuttgart: Thieme, 1996

Auditory Diagnosis
Silam, Shlomo and Carol A. Silvermann
San Diego / London: Singular Publishing Group, 1997

11 Individual Setup of the MI 26

The MI 26 offers many options for the experienced user to adapt the instrument to individual demands.

The settings shown in the figures are the standard settings. If you have altered a value by accident, you just have to return to the standard setting shown here and the instrument will work as before.

By pressing the **Menu** key (10) you can return from every sub-menu to the main menu and to the tympanometry mode.

You can change the menu options with the **up/down/left/right** cursor keys. The menu option selected is highlighted on the LCD
(**SETUP** in the example Figure 26).
Select the chosen menu option by pressing **Enter**.

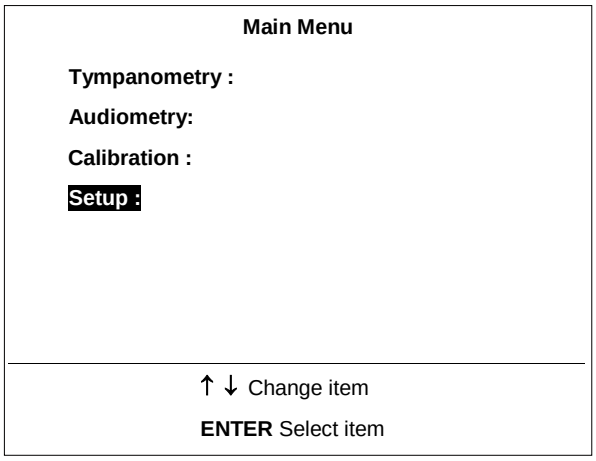


Figure 26
MI 26 main menu

11.1 The setup menu

Select the menu option **SETUP** as illustrated in Figure 26 and the main setup menu will appear on the LCD. You can make different settings for the measurement of the tympanogram and the Stapedius reflex as well as the instrument setup (for example the contrast of the LCD). All your settings are saved permanently until you will change them again. The settings also survive when the instrument is switched off.

11.2 The Tympanometer setup

Select the menu option **Tympanometry Setup Menu:** as illustrated in Figure 27 and the Tympanometer setup menu will appear on the LCD**.**

Change the menu options with the **up/down** cursor keys.

Change the displayed item with the **left/right** cursor keys. The following settings are possible:

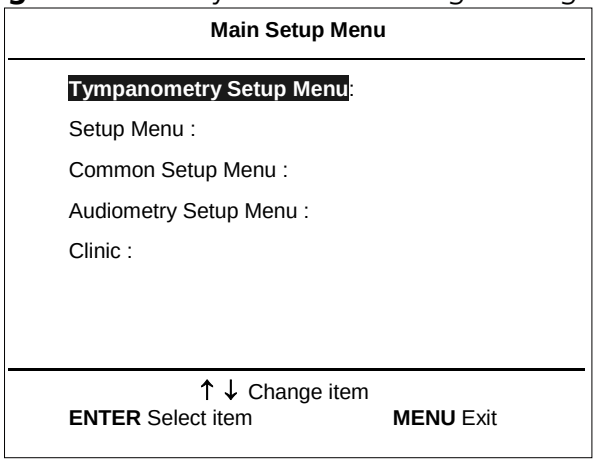


Figure 27
MI 26 setup menu

Pump speed:

With this option you can set the measurement speed. With **Automatic**, the pump speed adjusts automatically to the test conditions. It is possible to choose:

Minimum, **Medium** or **Maximum** as well. A lower pump speed creates a higher precision of the measurement but needs more test time.

Display limits:

ON Displays the field for normal curves surrounded by a broken line in the tympanogram.

OFF Turns it off.

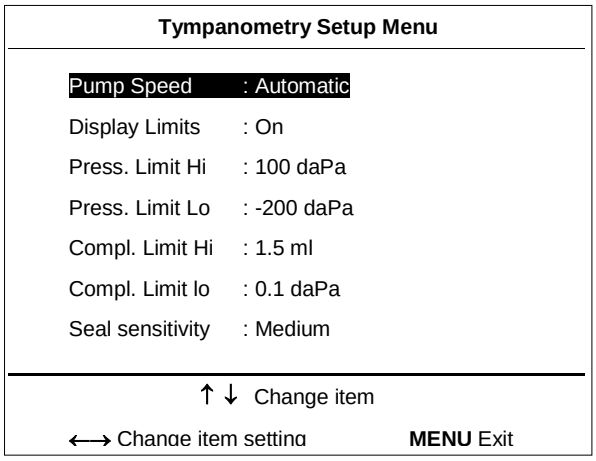

Tympanometry Setup Menu
Pump Speed : Automatic
Display Limits : On
Press. Limit Hi : 100 daPa
Press. Limit Lo : -200 daPa
Compl. Limit Hi : 1.5 ml
Compl. Limit lo : 0.1 daPa
Seal sensitivity : Medium
↑ ↓ Change item
←→ Change item setting
MENU Exit

Figure 28
MI 26 Tympanometer Setup Menu
(Pump speed selected)
(Display limits setup selected)

Press. Limit hi:

With this option you can set the right limit of the box for normal tympanograms to a value between 0 daPa and +200 daPa in steps of 25 daPa.

Press. Limit lo:

With this option you can set the left limit of the box for normal Tympanograms to a value between -400 daPa and -25 daPa in steps of 25 daPa.

Comp. limit hi:

With this option you can set the upper limit of the box for normal tympanograms to a value between 0.1 ml and 3 ml in steps of 0.1 ml.

Comp. limit lo: With this option you can set the lower limit of the box for normal tympanograms to a value between 0.1 ml and 1.0 ml in steps of 0.1 ml. To leave the **Tympanometry Setup Menu** press the **Menu** button.

Seal sensitivity:

Minimum: This gives reproducible results. Requires quiet probe handling.
Medium: Quicker seal detection and less sensitive than the above selection.
Maximum: Quick seal detection. AGC on the probe tone is disabled.

To leave the Tympanometry Setup Menu press the MENU button ⑧.

11.3 The Setup menu for Reflex Test

Select the menu option **Setup menu for Reflex Test** from the main setup menu as described before for the Tympanometry setup menu. The reflex setup menu will appear on the LCD**.**

The reflex setup menu offers the following options:

Auto start dB :

With this option you can choose the starting acoustic pressure level if the automatic identification of the reflex threshold is switched on. You can choose the acoustic pressure levels from 70 dB_{HL} to 100 dB_{HL} in steps of 5 dB.

Auto maximum dB:

With this option you can choose the maximum acoustic pressure level the MI 26 uses if the automatic identification of the reflex threshold is switched on. You can choose the maximum acoustic pressure levels from 70 dB_{HL} to 110 dB_{HL} in steps of 5 dB.

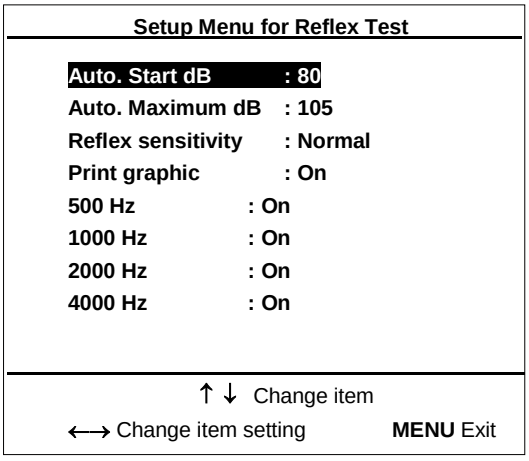

Setup Menu for Reflex Test
Auto. Start dB : 80
Auto. Maximum dB : 105
Reflex sensitivity : Normal
Print graphic : On
500 Hz : On
1000 Hz : On
2000 Hz : On
4000 Hz : On
↑ ↓ Change item
⟷ Change item setting
MENU Exit

Figure 30
MI 26 Reflex setup menu
(Auto start dB setup selected)

Reflex sensitivity:

With this option, select the sensitivity of the Stapedius reflex detection.

The **Sensitive** setting will achieve **Pass** as test results with very small compliance changes.

With the **Robust** setting a larger compliance change is needed to detect a **Pass**.

The **Normal** setting is the default setting.

Print graphic:

With this option the printout of the graphic reflex display can be turned on or off for documentation.

500 Hz : The Stapedius reflex test can be turned on and off with this option.

1000 Hz : The Stapedius reflex test can be turned on and off with this option.

2000 Hz : The Stapedius reflex test can be turned on and off with this option.

4000 Hz : The Stapedius reflex test can be turned on and off with this option.

To leave the Setup Menu for reflex, press the **Menu** button.

The Common Setup Menu

Select the menu option **Common Setup Menu** from the main setup menu.

The common setup menu offers the following options.

Power-up:

Choose the test mode of the MI 26 after switching on. With the setting **Tymp** , only tympanometry is tested after power-up.

With **Tymp and Reflex** tympanometry and reflex are tested after power-up.

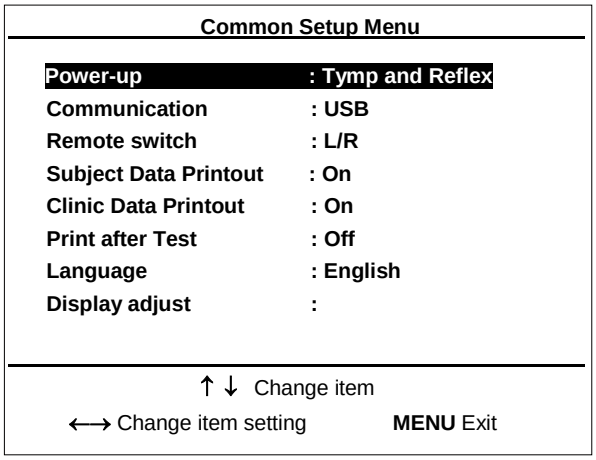


Figure 30
MI 26 Reflex setup menu
(Auto start dB setup selected)

Communication USB:

This is only the reference to the USB interface.

Remote Switch:

Change the function of the probe button. You can choose between:

L/R the test ear can be selected with the probe button.

Pause the test can be paused and restarted with the probe button.

L/R or Pause both the test ear and the test can be selected, paused and restarted with the probe button (M) or **OFF** .

Subject Data Printout :

Turn the printout of the headline (data entry area at the top) on or off.

Clinic Data Printout :

If you entered your clinic data the printout of the entered data can be switched **ON** and **OFF** this option**.**

Print after test :

With this option you enable an automatic printout after you finished a test by setting it **ON** . With the setting **OFF** the printout will be processed after you press the **Print** button.

Language :
You can choose one of the following languages:

Deutsch	German
Francais	French
English	English
Espanol	Spanish

For the text on the LCD and the printout. After selection all the texts appear in the chosen language.

Display adjust :
The contrast of the LCD can be changed with this option.

11.4 Audiometer Setup Menu

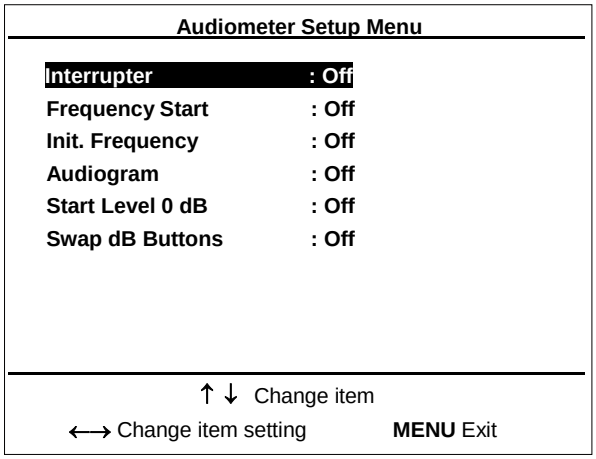


Figure 31
MI 26 Audiometer setup menu

Interrupter:
OFF: when selected the stimulus key is in the presentation mode, and will present a tone when pressed.
ON: the stimulus key is in the interrupt mode, with the tone always on until the stim key is pressed.

Frequency Start:
ON: the dB level will drop 20 dB from the current level when changing frequencies.

Init. Frequency:
OFF: while scrolling through audiometer frequencies using the ◂ ▸ keys, the next available frequency will roll from 8000 to 125 Hz or from 125 to 8000 Hz.
ON: while scrolling through frequencies using the ◂ ▸ keys, the next available frequency will roll from 8000 to 1000 Hz or from 125 to 1000 Hz.

Audiogram:
OFF: test data is displayed in tabular form
ON: test data is displayed as an audiogram.

Start Level 0 dB:
OFF: the starting dB test level at each new frequency setting starts where initially set.
ON: at each new frequency setting the starting dB will drop to 0 dB.

Swap dB Buttons:
OFF: The level will be increased with the ▲ key and decreased with the ▼ key.
ON: The level will be increased with the ▼ key and decreased with the ▲ key.

11.5 Insert your personal printout data

Select the menu option **Clinic Setup menu** from the main setup menu, see Figure 27, to enter all required data for your clinic. These data will be printed out with the test result and the patient data.

12 Care and maintenance of the instrument

Disconnect the power plug before cleaning.

To clean the instrument, probe, contralateral receiver and other accessories use a soft, damp cloth (use warm soapy water; no liquids containing alcohol or ammonia should be used) to gently wipe the area clean.

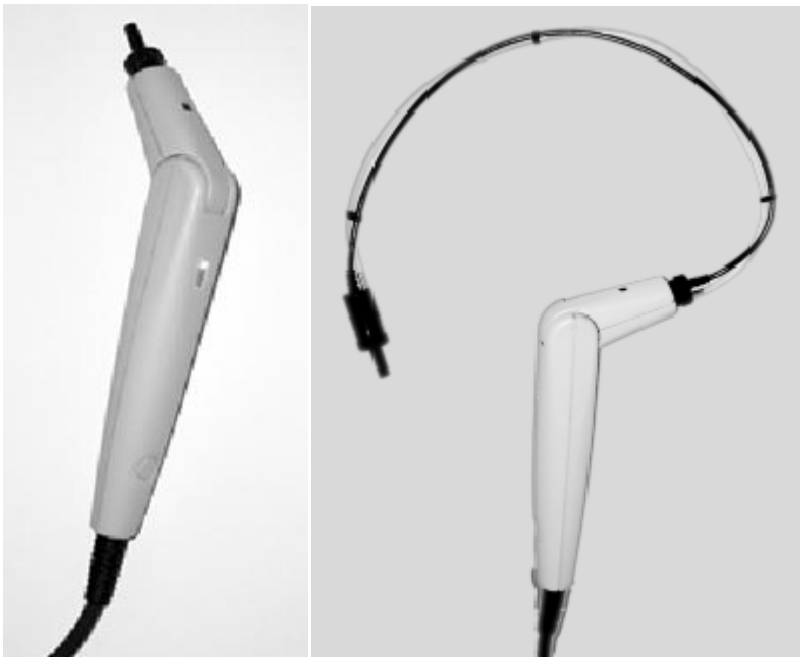
During cleaning, please ensure that no liquid runs into the switches, level control or probe openings.

Please use a new eartip for each patient. Always use eartips from MAICO or Sanibel. Each eartip should only be used one time.

12.1 Cleaning of Probe Tip

In order to secure correct impedance measurements it is important to make sure that the probe system is kept clean at all times. Therefore please follow the below illustrated instruction on how to remove e.g. cerumen from the small acoustic and air pressure channels of the probe tip.
For the MI 26 two different probe systems exist; the Screening Probe System and the Diagnostic Probe System.
The two different probe systems can be seen in the below picture:

Figure 32:

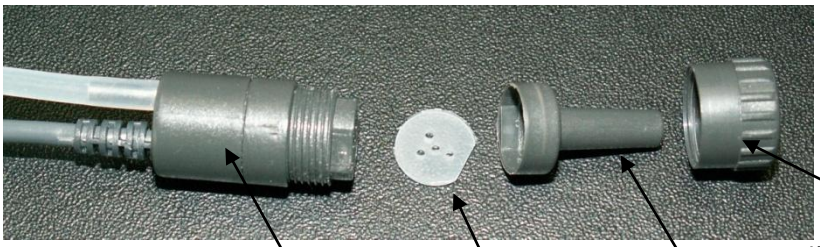


To clean the small acoustic and air pressure channels of the probe tip unscrew the small ribbed plastic nut that holds the probe tip:

Figure 33:

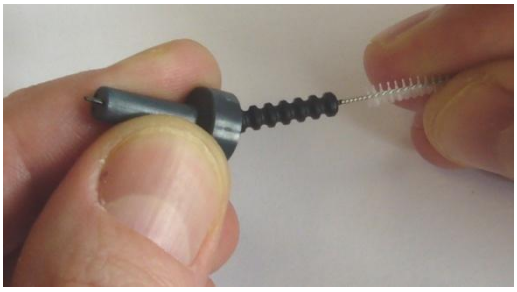
After unscrewing the small ribbed plastic nut it is possible to detach the small probe tip with the small acoustic and air pressure channels from the transducer house:

Figure 34:



The cleaning of the acoustic and air pressure channels of the probe tip must be performed by means of the cleaning wire which can be found in the Ear tips Assortment provided with the MI 26.
When cleaning the acoustic and air pressure channels of the probe tip the cleaning wire must be inserted from the back of the probe tip according to Figure 35:

Figure 35:



Besides cleaning the holes ensure also a proper surface cleaning of the transparent sealing.
After cleaning all the acoustic and air pressure channels of the probe tip it can be reassembled. Make sure that the Probe Tip is connected correctly onto the Transducer Housing – a small flange will ensure correct positioning - before the plastic nut is gently tightened.

Figure 36:

Figure 37:

The cleaning tool: (Consisting of 3 parts: cleaning hooks, wire with brush and hand grip)

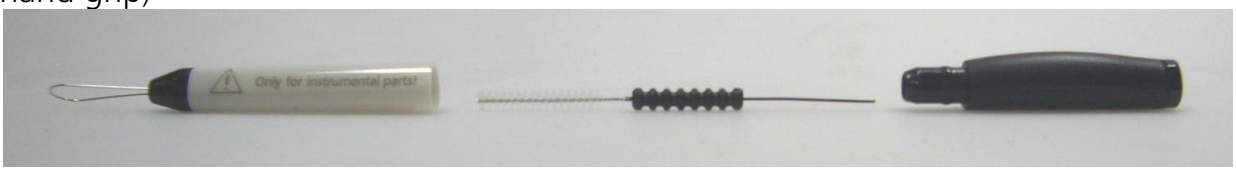


Figure 38:

With the hook of the cleaning tool you can remove cerumen from the ear tips.

13 Disinfection

It is recommended that parts which are in direct contact with the patient are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

To avoid person-to-person cross contamination of communicable diseases eartips should only be used one time.

14 How to change the printer paper

At the right side of the housing, pull the printer cover up using its finger recess in the front of the printer cover.

Remove the printer cover.

Remove the empty paper roll.

Place the new paper roll in the paper compartment in such a way that the paper unrolls from the **bottom side** of the roll.

Pull the blue lever, which is located on the right front of the printer, forward into position.

The paper must feed from the bottom because it is only coated on one side. **If it is inserted wrong, no printout will be visible!**

Gently insert the paper end in between the rubber roll and the black plastic part at the rear of the printer.

Feed the printer paper until it appears from the upper part of the rubber roll.

Feed about 4 – 5 cm of paper from the roll.

Push the blue lever back into its backward position.

Guide the paper end through the paper slot of the printer cover.

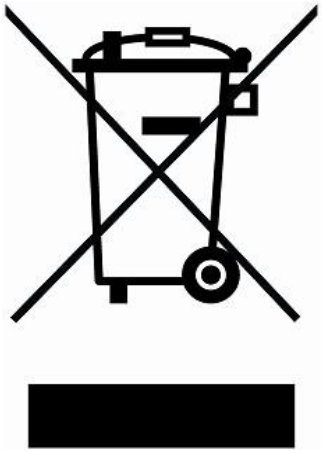
Close the printer cover by putting the two guide rails at the end of the printer cover into their appropriate slots in the paper compartment of the housing of the MI 26. Press the front of the printer cover down until it fastens.

You are now ready to print.

15 Warranty, Maintenance and After-Sales Service

The MI 26 Tympanometer is guaranteed for 1 year. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.
The tympanometer may be repaired only by your dealer or by a service centre recommended by your dealer. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.
In the event of repair during the guarantee period, please enclose evidence of purchase with the instrument.
In order to ensure that your instrument works properly the tympanometer should be checked and calibrated at least once a year. This check has to be carried out by your dealer.
When returning the instrument for repairs it is essential to also send the probe and all other accessories.
Send the device to your dealer or to a service centre authorized by your dealer.
Please also include a detailed description of the faults.
In order to prevent damage in transit, please use the original packing if possible when returning the instrument.

NOTE:



Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste of electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

16 Safety Regulations

16.1 Electrical Safety:

The MI 24 tympanometer is constructed to comply with protection class I, Type BF of the international standard IEC 601-1
(EN 60601-1).
Protection from an electric shock is ensured even without the system earth connection.
The instruments are not intended for operation in areas with an explosion hazard.

16.2 Measuring security:

To guarantee that the tympanometer works properly, the instrument has to be checked and calibrated at least once a year.
The service and calibration must be performed by an authorized service centre. In accordance with the regulations of the EU medical directive we will drop our liability if these checks are not done.
The use of non-calibrated tympanometers is not allowed.

16.3 Device control:

The user of the instrument should perform a subjective instrument check once a week. This check can be done following the list for subjective instrument check (see next page). For your own security, you should copy the enclosed list, fill it in once a week and store it in your files.

16.4 Operation:

Only skilled personnel (Audiologists, ENT professionals or other with equivalent knowledge) should operate the instrument.

16.5 Patient Safety:

Warning: Do not take a test while charging the device via USB cable.
External equipment intended for connection to signal input, signal output or other connector, shall comply with relevant IEC standard (e.g. IEC 60950 for IT equipment and the IEC 60601 series for medical electrical equipment). In addition, all such combinations - systems - shall comply with the standard 60601-1-1, Safety requirements for medical electrical systems. Equipment not complying with IEC 60601 shall be kept outside patient environment, as defined in the standard

(at least 1.5 m from the patient).

Any person who connects external equipment to signal input, signal output or other connectors has created a system and is therefore responsible for the system complying with the requirements of IEC 60601-1-1. If in doubt, contact your service technician or local representative for help.

The cradle connection provides power for the thermal printer.
In order to maintain a high level of safety it is necessary to have the instrument and its power supply checked according to the medical electrical safety standard IEC 60601-1 on a yearly basis by a qualified service technician.

17 Checklist for subjective device control

According to the manufacturer requirements, the user should test the instrument once a week. This is to find errors immediately and to avoid wrong test results. This test should test tympanogram and reflex with an otologic normal person and compare the results with earlier measurements. The printout should be filed together with the subjective test protocol to document the instrument test. The test person should be healthy (no otitis etc.) and should not be exposed to loud noise for at least 12 hours before the test.

Instrument type:

Serial-No.:

Attach the printout of tympanogram and reflex test for both ears.

Test person:

Connectors and cables OK?

Instrument and probe?

Is the green light (O) of the probe blinking?

Probe tip and ear tip clean?

Are all controls easy to use?

Are the test signals clear and non-distorted?

Reflex test right ear 90 dB_{HL}	500 Hz	1000 Hz	2000 Hz	4000 Hz
Reflex test left ear 90 dB_{HL}	500 Hz	1000 Hz	2000 Hz	4000 Hz

If significant differences or damages are found, please send in for service repair.

Tested by: Date:

List for the subjective instrument checks

- Clean the cushions of the head phones! - If necessary untangle all cords - Are the cushions of the headphones all right? If not replace them! - Are the connectors and cables damage free? - Can all operator elements be handled smoothly ? - Are the operator elements over- tightened or damaged? - Is the patient response system O.K. ?	Model..... Manufacturer..... Serial No..... Test person.....

Purity of test signals

Try all test frequencies at the HL settings of the table and if necessary enter :
"B" for humming, "G" for noises, "V" for signal distortion , "S" for switching noises

	Right Ear								Level	Left Ear								
kHz	25	5	1	2	3	4	6	8		25	5	1	2	3	4	6	8	kHz
AC									30dB HL									
									50dB HL									
									70dB HL									
BC									30dB HL									
									50dB HL									

* in the event that disturbed noises "B", "G", "V" or "S" have been checked then SERVICE!
* If conduction test signals are also audible in the non-test ear, then SERVICE!

Air conduction audiogram with test person

	Right Ear								Level	Left Ear								
kHz	25	5	1	2	3	4	6	8		25	5	1	2	3	4	6	8	kHz
Right phone									Target dBHL									
left phone									Actual dBHL									left phone
right phone									Actual dBHL									right phone

* desired value is the measured value of the last audiogram of the test person
**Repeat the measurement with head phones on the wrong way around
If the difference between desired and actual value at a particular frequency or between right and left headphones is more than 10 dB, then SERVICE !
If the difference between desired and actual value at a particular frequency or between right and left headphones is more than 10 dB, then SERVICE

Tested:.....
Date:.....

18 Technical Data and Accessories

CE 0123

The Impedance meter MI 26 is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

Impedance measurement:

Type: Class 2 acc. to IEC 645-5 (EN 60645-5)

Tympanometer:

Test frequency: 226 Hz ± 1%
Test level: 85 dB_{SPL} in 2 cm3

Pressure range: +200 to -400 daPa
Volume range: 0,1 to 6,0 ml
Accuracy: ± 5 % or ± 10 daPa
Compliance range: 0,1 to 6,0 ml

Reflex measurement:

Test frequencies: 500 Hz, 1 kHz, 2 kHz, 4 kHz ± 2%
Test method: ipsi lateral, contra lateral
Intensities ipsi: 70 dB_{HL} ... 100 dB_{HL}
Intensities contra: 70 dB_{HL} ...105 dB_{HL} (with button contra phone)
(for 4 kHz ... 100 dB_{HL})
70 dB_{HL} ... 110 dB_{HL} (with TDH 39 contra phone)
Attack/release time: typical 10 ms
Pressure at test: Pressure @ max. compliance
Audiometer: Class 4 acc. to IEC 60 645-1
Test frequencies: 250 Hz, 500 Hz, 1 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz, 8 kHz
Test level: 5 dB noise free, with TDH 39 0 dB_{HL} … 90 dB_{HL}
Test signal: Pure tone or pulse tone (selectable)
Modulation: on/off time 0,4 s
Interrupter: also in setup changeable to presentation mode

General:

Memory: Storage of two complete test result sets
LCD-display: Graphical display of the tympanograms and the reflex curves

Numeric display of max. compliance, pressure at

	max. Compliance, canal volume, gradient and reflex thresholds
Printer:	Thermal printer, paper roll width 110 mm
Printing time:	Between 4 seconds (one tympanogram) and 12 seconds (tympanogram and reflex for both ears)
Voltage:	100 - 240 V / 50/60 Hz
Power consumption:	25 VA

Connection plugs:	Connection	Specification
A. Power socket	left/right=power,	100…240 V~ 50/60 Hz
B. Pressure tube		
C. Probe		
D. PC-interface		USB
E. Contra lateral phone (option)	sleeve=GND, tip=out	Z_A=10 Ω, U_A=8V_{eff}
F. AC (headphone) right channel	sleeve=GND, tip=out	Z_A=10 Ω, U_A=8V_{eff}
G. AC (headphone) left channel	sleeve=GND, tip=out	Z_A=10 Ω, U_A=8V_{eff}
H. PAT – patient response switch	sleeve=GND, tip=in	R_I=100 k Ω

Warm up time:	less than 10 min after power on
Environment conditions:	+ 15 to + 35 °C / + 59 to + 95 °F (operation) + 5 to + 50 °C / + 41 to + 122 °F (storage) Maximum humidity 90 % (storage and operation)
Dimensions:	(15 ¼" W x 11 1/2" D x 4 ¼" H) (W x D x H 39 cm x 29 cm x 11 cm)
Weight:	appr. 2,6 kg (5 ½ Lbs)

Accessories:

Standard:

1 hand-held probe
1 power cable
1 set of ear Tipps (24 pieces)
1 calibration test cavity
(cavities 5ml, 2ml, 0,5ml, 0,2ml)
1 printer paper roll (for app. 350 printouts)
1 TDH 39 headset
1 Patient response switch

Consumable:

1 roll printer paper	Part No.705 078
4 pc. ear tips yellow (7 mm)	Part No.705 056
4 pc. ear tips green (9 mm)	Part No.705 057
4 pc. ear tips white (11 mm)	Part No.705 058
4 pc. ear tips yellow (13 mm)	Part No.705 059
4 pc. ear tips green (15 mm)	Part No.705 060
4 pc. ear tips blue (18 mm)	Part No.705 061

Calibration values:

Receiver Telephonics TDH 39 Force: 4,0 ... 5,0 N

Frequency [Hz]	Reference equivalent threshold sound pressure level ISO 389 - 1 with Coupler IEC 318-2 [dB] (re 20 µPa)	Sound damping [dB]
250	25.5	5
500	11.5	7
1000	7	15
2000	9	26
3000	10	-
4000	9.5	32
6000	15.5	-
8000	13	24

Specifications are subject to change.

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